



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA-2014-D-1856]

Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue:

Regulatory Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments on draft guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry” dated December 2014. The draft guidance document provides sponsors, clinicians, and other establishments that manufacture and use adipose tissue, with recommendations for complying with the regulatory framework for HCT/Ps. For purposes of applying the HCT/P regulatory framework, FDA considers connective tissue, including adipose tissue, to be a structural tissue. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002 or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or you may send an email request to the Office of Combination Products at [combination@fda.gov](mailto:combination@fda.gov). If you are submitting a written request, send one self-addressed adhesive label to assist that office in processing your request. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Angela Krueger, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5127, Silver Spring, MD 20993-0002, email: [combination@fda.gov](mailto:combination@fda.gov).

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft document entitled “Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry” dated December 2014. FDA has recently received numerous inquiries regarding HCT/Ps from adipose tissues. This draft guidance document provides sponsors, clinicians, and other establishments that manufacture and use HCT/Ps from adipose tissue with the Agency’s current thinking with respect to regulatory considerations for adipose tissue.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

### II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910-0543.

### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments

regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> or <http://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of the draft guidance entitled “Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry,” may send an email request to [CDRH-guidance@fda.hhs.gov](mailto:CDRH-guidance@fda.hhs.gov) to receive an electronic copy of the document.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-30142 Filed 12/23/2014 at 8:45 am; Publication Date: 12/24/2014]